Docket No. COD5001USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Rosenberg Meir	Confirmation No.:	9738
Appln. No.	: 10/601,455	Art Unit :	3761
Filed	: June 23, 2003	Examiner :	DEAK, LESLIE R
Title	: Implantable Medical Device Having Pressure Sensors For Diagnosing The Performance Of An Implanted Medical Device		

CERTIFICATE OF TRANSMISSION			
I hereby certify that this correspondence is being electronically filed via EFS-Web to the Commissioner for Patents with the U.S. Patent and Trademark Office on: June 1, 2010			
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in response to the Notice of Appeal, which was mailed by Appellant to the U.S. Patent & Trademark Office on January 19, 2010, which was filed in response to the Final Office Action of November 16, 2009.

Real Party In Interest:

By virtue of an assignment recorded at reel/frame 014228 / 0428, the real party in interest for this patent application is Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham 02767, which is wholly owned by Johnson & Johnson, a New Jersey corporation.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claim 42 have been cancelled.

Claims 1-41 and 43-46 are pending, have been finally rejected, and are hereby appealed.

Status of Amendments:

No amendments have been filed after the final rejection of November 16, 2009.

Summary of Claimed Subject Matter:

Independent Claim 1

The present invention, as exemplified by independent claim 1 is directed to an implantable medical device comprising a housing 12 and a valve 14 disposed within the housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered first pressure sensor 16 is disposed within the housing 12 and upstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered second pressure sensor 18 is disposed within housing 12 and downstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered CPU 20 is disposed within housing

12 and is operatively connected to the first pressure sensor 16 and the second pressure sensor 16. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4)

Independent Claim 18

The present invention, as exemplified by independent claim 18 is directed to an implantable medical device comprising a housing 12 and a valve 14 disposed within the housing. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered first pressure sensor 16 disposed within housing 12 and upstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered second pressure sensor 18 is disposed within housing 12 and downstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered CPU 20 is operatively connected to first pressure sensor 16 and second pressure sensor 18. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4)

Independent Claim 21

The present invention, as exemplified by independent claim 21 is directed to a method for diagnosing the performance of an implanted medical device 10. The implanted medical device 10 has a housing 12 and a valve 14 disposed within housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered first pressure sensor 16 is disposed within housing 12 and upstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered second pressure sensor 18 is disposed within housing 12 and downstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered CPU 20 is disposed within housing 12 and is operatively connected to first pressure sensor 16 and second pressure sensor 18. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4)

The method comprises the steps of:

comparing the pressure measured by the first pressure sensor 16 to the pressure measured by the second pressure sensor 18; (See, *e.g.*, Page 6, lines 9-20, Figures 1-4) and

wirelessly communicating the compared pressures to an external device. (See, *e.g.*, Page 6, lines 9-20, Figures 1-4)

Independent Claim 24

The present invention, as exemplified by independent claim 24 is directed to a method of diagnosing the performance of an implanted medical device 10. The implanted medical device 10 has a housing 12 and a valve 14 disposed within housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered first pressure sensor 16 is disposed within housing 12 and upstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered second pressure sensor 18 is disposed within housing 12 and downstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered CPU 20 is disposed within housing 12 and is operatively connected to first pressure sensor 16 and second pressure sensor 18. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4)

The method comprising the steps of:

determining by the CPU, the pressure detected by the first pressure sensor; (See, *e.g.*, Page 6, lines 9-20, Figures 1-4)

determining by the CPU, the pressure detected by the second pressure sensor; (See, *e.g.*, Page 6, lines 9-20, Figures 1-4) and

wirelessly communicating the determined pressures to an external device. (See, *e.g.*, Page 6, lines 9-20, Figures 1-4) (page 6, lines 9-16)

Independent Claim 25

The present invention, as exemplified by independent claim 25 is directed to an implantable medical device comprises a housing 12 and a valve 14 disposed within

housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A valve 14 is disposed within housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered differential pressure sensor 50 is disposed within housing 12. (See, *e.g.*, Page 5, lines 11-23, Figures 5 and 6). A non-invasively wirelessly powered CPU 20 is disposed within housing 12 and is electrically connected to differential pressure sensor 50. (page 5, lines 24-27, Figure 6)

Independent Claim 37

The present invention, as exemplified by independent claim 37 is directed to a method of diagnosing the performance of an implanted medical device wherein the implanted medical device has a housing 12 and a valve 14 disposed within housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered differential pressure sensor 50 is disposed within housing 12. (See, *e.g.*, Page 5, lines 11-23, Figures 5 and 6). A non-invasively wirelessly powered CPU 20 is disposed within housing 12 and is electrically connected to differential pressure sensor 50. (page 5, lines 24-27, Figure 6)

The method comprising the steps of:

determining by the CPU 20, the pressure detected by the differential pressure sensor 50; (See, *e.g.*, Page 6, lines 9-20, Figures 1-4) and

wirelessly communicating the determined pressure to an external device. (page 6, lines 9-14) (See, *e.g.*, Page 6, lines 9-20, Figures 1-4)

Independent Claim 38

The present invention, as exemplified by independent claim 38 is directed to a method for diagnosing the performance of an implanted medical device 10. The implanted medical device 10 has a housing 12 and a valve 14 disposed within housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered first pressure sensor 16 is disposed within housing 12 and upstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered

second pressure sensor 18 is disposed within housing 12 and downstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4)

The method comprising the steps of:

wirelessly communicating a signal representative of the pressure detected by the first pressure sensor 16 to an external device; page 6, lines 9-16)

wirelessly communicating a signal representative of the pressure detected by the second pressure sensor 18 to an external device; page 6, lines 9-16) and

comparing the pressure detected by the first pressure sensor 16 to the pressure detected by the second pressure sensor 18 with the external device. (page 6, lines 9-16)

Independent Claim 39

The present invention, as exemplified by independent claim 39 is directed to a method for diagnosing the performance of an implanted medical device, wherein the implanted medical device has a housing 12 and a valve 14 disposed within housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered first pressure sensor 16 is disposed within housing 12 and upstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered second pressure sensor 18 is disposed within housing 12 and downstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4)

The method comprising the steps of:

generating a signal from the first pressure sensor 16; (page 6, lines 3-8)

generating a signal from the second pressure sensor 18; (page 6, lines 3-8)

comparing the signals from the first pressure sensor 16 and the second pressure sensor 18; (page 6, lines 3-8)

generating a signal representative of the difference in pressure between the pressure measured by the first pressure sensor and the pressure measured by the second pressure sensor; (page 6, lines 3-8)

wirelessly communicating the signal representative of the difference in pressure to an external device. (page 6, lines 3-8)

Independent Claim 40

The present invention, as exemplified by independent claim 40 is directed to an implantable medical device comprising a housing 12 and a valve 14 disposed within the housing 12. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered first pressure sensor 16 is disposed within the housing 12 and upstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4) A non-invasively wirelessly powered second pressure sensor 18 is disposed within housing 12 and downstream of valve 14. (See, *e.g.*, Page 3, line 31 - Page 4, line 7, Figures 1-4)

Grounds of Rejection To Be Reviewed On Appeal:

A) Whether the final rejections stating that claims 1-41 and 43-46 are unpatentable under 35 U.S.C. 103(a) should be reversed.

Argument:

Rejection of claims 1-24, 38-44, and 46 under 35 USC 103(a)

The Examiner has finally rejected claims 1-24, 38-44, and 46 under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al (hereinafter referred to as "Cowan"), in view of US 6,248,080 to Miesel et al (hereinafter referred to

as "Miesel"), further in view of US 7,371,223 to Couvillon, Jr. et al (hereinafter referred to as "Couvillon").

Rejection of claims 25-30, 37, and 45 under 35 USC 103(a)

The Examiner has finally rejected claims 25-30, 37, and 45 under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman (hereinafter referred to as "Cosman"), further in view of US 7,371,223 to Couvillon, Jr. et al.

Each of the independent claims have been amended during the prosecution of the present application to positively recite that either the first and second pressure sensors, the differential pressure sensor and/or the CPU is non-invasively wirelessly powered. In response to this amendment, the Examiner has admitted that both Cowan and Miesel fail to disclose that the pressure sensors and controllers are non-invasively wirelessly powered. The Examiner is relying on Couvillon for the teaching of an implantable fluid control device (a bypass pump) "that may use waveform data sent to a receiver *that powers* an implanted component in order to reduce size of the control unit" and ""depending on the procedure time ... a battery **can** be used as a source for power." (emphasis added) The Examiner points to column 12, line 28-39 and 53-55 of Couvillon for support of these statements. The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to use wireless, non-invasive power, such as that disclosed by Couvillon, to supply power to the apparatus suggested by Cowan and Miesel to reduce the size of the controller, as taught by Couvillon.

Couvillon does not teach an implantable fluid control device (a bypass pump) that uses waveform data sent to a receiver that powers an implanted component in order to reduce size of the control unit, despite the Examiner's assertion. Couvillon

only teaches sending control data (*e.g.*, waveform data) over a wireless communications interface. *See* column 12, lines 28-30 of Counvillon. "The received waveform data can then be routed to drivers, which power the actuators within the pump." Column 12, lines 38-39. Control unit 150 is provided with a source of power (*e.g.*, a battery). Column 12, lines 52-55. "Data is exchanged with the control unit 250 of the bypass pump via a wireless communication interface. Wireless interface 164a, which is associated with the control and user interface262, communicates with a remote companion wireless interface 164b, which is associated with the control unit 250." Column 12, lines 52-58. Nowhere does Couvillon teach or suggest that the wireless communication powers an implanted component. In fact, Couvillon teaches away from wirelessly powering the implanted component by making it expressly clear that the implant control unit 150 is provided with its own source of power. Thus, the Examiner has failed to establish a *prima facia* case of obviousness. Therefore, the present application is in condition for allowance and an early indication of such is respectfully requested.

B) Whether the final rejections stating that claims 15-17 and 31-36 are unpatentable under 35 U.S.C. 103(a) should be reversed.

Rejection of claims 15-17 under 35 USC 103(a)

The Examiner has finally rejected claims 15-17 under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 6,248,080 to Miesel et al., in view of US 7,371,223 to Couvillon, Jr. et al, further in view of US 2003/0004495 to Saul et al.

Rejection of claims 34-36 under 35 USC 103(a)

The Examiner has finally rejected claims 34-36 under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, in view of US 7,371,223 to Couvillon, Jr. et al, further in view of US 2003/0004495 to Saul et al.

Rejection of claims 31-33 under 35 USC 103(a)

The Examiner has finally rejected claims 31-33 under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, in view of US 7,731,223 to Couvillon, Jr. et al, further in view of US 6,428,080 to Miesel.

The rejection of dependent claims 15-17 and 31-36 stand or fall with the determination by the Board of Appeals with respect to each dependent claim's respective independent claim.

Conclusion:

For the reasons discussed above, Appellants maintain that the Examiner's final rejection of claims 1-41 and 43-46 under 35 USC § 103(a) should be reversed.

Respectfully submitted,

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Claims Appendix

An appendix containing a copy of the claims involved in the appeal.

1. (Previously presented) An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered first pressure sensor disposed within said housing and upstream of said valve;

a non-invasively wirelessly powered second pressure sensor disposed within said housing and downstream of said valve; and

a non-invasively wirelessly powered CPU disposed within said housing and being operatively connected to said first pressure sensor and said second pressure sensor.

2. (Original) The device according to claim 1, wherein the CPU is electrically connected to said first pressure sensor and said second pressure sensor.

3. (Previously presented) The device according to claim 2, wherein the CPU has means for wirelessly communicating is adapted to communicate within an external device.

4. (Previously presented) The device according to claim 3, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor.

5. (Previously presented) The device according to claim 1, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor.

6. (Original) The device according to claim 1, further comprising a first catheter fluidly connected to said housing, and a third pressure sensor disposed within said first catheter.

7. (Original) The device according to claim 6, wherein said third pressure sensor is operatively connected to said CPU.

8. (Original) The device according to claim 7, wherein said first catheter is fluidly connected to said housing upstream of said valve.

9. (Previously presented) The device according to claim 8, wherein the CPU has means for wirelessly communicating is adapted to communicate with an external device.

10. (Previously presented) The device according to claim 9, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor, and for calculating a differential pressure between the third pressure sensor and at least one of the first pressure sensor and the second pressure sensor.

11. (Original) The device according to claim 10, further comprising a second catheter fluidly connected to said housing, and a fourth pressure sensor disposed within said second catheter.

12. (Original) The device according to claim 11, wherein said fourth pressure sensor is electrically connected to said CPU.

13. (Original) The device according to claim 12, wherein said second catheter is fluidly connected to said housing downstream of said valve.

14. (Previously presented) The device according to claim 13, wherein the CPU has means for calculating a differential pressure between the first pressure sensor and the second pressure sensor and for calculating a differential pressure between the fourth pressure sensor and at least one of the first pressure sensor, the second pressure sensor and the third pressure sensor.

15. (Previously presented) The device according to claim 1, wherein the CPU has means for being is non-invasively powered using RF.

16. (Previously presented) The device according to claim 1, wherein the CPU has means for being is non-invasively powered using acoustics.

17. (Previously presented) The device according to claim 1, wherein the CPU has means for being is non-invasively powered using optics.

18. (Previously presented) An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered first pressure sensor disposed within said housing and upstream of said valve;

a non-invasively wirelessly powered second pressure sensor disposed within said housing and downstream of said valve; and

a non-invasively wirelessly powered CPU being operatively connected to said first pressure sensor and said second pressure sensor.

19. (Original) The implantable medical device according to claim 18, wherein said CPU is disposed within said housing.

20. (Original) The implantable medical device according to claim 18, wherein said CPU is disposed external to said housing.

21. (Previously presented) A method for diagnosing the performance of an implanted medical device, wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered first pressure sensor disposed within said housing and upstream of said valve;

a non-invasively wirelessly powered second pressure sensor disposed within said housing and downstream of said valve; and

a non-invasively wirelessly powered CPU disposed within said housing and being operatively connected to said first pressure sensor and said second pressure sensor,

the method comprising the steps of:

comparing the pressure measured by the first pressure sensor to the pressure measured by the second pressure sensor; and

wirelessly communicating the compared pressures to an external device.

22. (Original) The method according to claim 21, wherein the device further has a first catheter fluidly connected to said housing, and a third pressure sensor disposed within said first catheter, said method further comprising the steps of:

comparing the pressure measured by the third pressure sensor to one of the pressure measured by the first pressure sensor and second pressure sensor.

23. (Original) The method according to claim 22, wherein the device further comprising a second catheter fluidly connected to said housing, and fourth pressure

sensor disposed within said second catheter, said method further comprising the step of:

comparing the pressure measured by the fourth pressure sensor to one of the pressure measured by the first pressure sensor, the second pressure sensor and third pressure sensor.

24. (Previously presented) A method of diagnosing the performance of an implanted medical device wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered first pressure sensor disposed within said housing and upstream of said valve;

a non-invasively wirelessly powered second pressure sensor disposed within said housing and downstream of said valve; and

a non-invasively wirelessly powered CPU disposed within said housing and being operatively connected to said first pressure sensor and said second pressure sensor,

the method comprising the steps of:

determining by the CPU, the pressure detected by the first pressure sensor;

determining by the CPU, the pressure detected by the second pressure sensor; and

wirelessly communicating the determined pressures to an external device.

25. (Previously presented) An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered differential pressure sensor disposed within said housing ; and

a non-invasively wirelessly powered CPU disposed within said housing and being electrically connected to said differential pressure sensor.

26. (Previously presented) The device according to claim 25 wherein the CPU has means for wirelessly communicating is adapted to communicate within an external device.

27. (Previously presented) The device according to claim 25, further comprising a first catheter fluidly connected to said housing, and a non-invasively wirelessly powered second pressure sensor disposed within said first catheter.

28. (Original) The device according to claim 27, wherein said second pressure sensor is operatively connected to said CPU.

29. (Original) The device according to claim 28, wherein said first catheter is fluidly connected to said housing upstream of said valve.

30. (Previously presented) The device according to claim 29, wherein the CPU has means for wirelessly communicating is adapted to communicate within an external device.

31. (Original) The device according to claim 30, further comprising a second catheter fluidly connected to said housing, and a third pressure sensor disposed within said second catheter.

32. (Original) The device according to claim 31, wherein said third pressure sensor is operatively connected to said CPU.

33. (Original) The device according to claim 32, wherein said second catheter is fluidly connected to said housing downstream of said valve.

34. (Previously presented) The device according to claim 25, wherein the CPU has means for being is non-invasively powered using RF.

35. (Previously presented) The device according to claim 25, wherein the CPU has means for being is non-invasively powered using acoustics.

36. (Previously presented) The device according to claim 25, wherein the CPU has means for being is non-invasively powered using optics.

37. (Previously presented) A method of diagnosing the performance of an implanted medical device wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered differential pressure sensor disposed within said housing; and

a non-invasively wirelessly powered CPU disposed within said housing and being electrically connected to said differential pressure sensor,

the method comprising the steps of:

determining by the CPU, the pressure detected by the differential pressure sensor; and

wirelessly communicating the determined pressure to an external device.

38. (Previously presented) A method for diagnosing the performance of an implanted medical device, wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered first pressure sensor disposed within said housing and upstream of said valve; and

a non-invasively wirelessly powered second pressure sensor disposed within said housing and downstream of said valve;

the method comprising the steps of:

wirelessly communicating a signal representative of the pressure detected by the first pressure sensor to an external device;

wirelessly communicating a signal representative of the pressure detected by the second pressure sensor to an external device; and

comparing the pressure detected by the first pressure sensor to the pressure detected by the second pressure sensor with the external device.

39. (Previously presented) A method for diagnosing the performance of an implanted medical device, wherein the implanted medical device has:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered first pressure sensor disposed within said housing and upstream of said valve; and

a non-invasively wirelessly powered second pressure sensor disposed within said housing and downstream of said valve;

the method comprising the steps of:

generating a signal from the first pressure sensor;

generating a signal from the second pressure sensor;

comparing the signals from the first pressure sensor and the second pressure sensor;

generating a signal representative of the difference in pressure between the pressure measured by the first pressure sensor and the pressure measured by the second pressure sensor;

wirelessly communicating the signal representative of the difference in pressure to an external device.

40. (Previously presented) An implantable medical device comprising:

a housing;

a valve disposed within said housing;

a non-invasively wirelessly powered first pressure sensor disposed within said housing and upstream of said valve; and

a non-invasively wirelessly powered second pressure sensor disposed within said housing and downstream of said valve.

41. (Previously presented) The device according to claim 1, wherein said first pressure sensor and said second pressure sensor are disposed on a common substrate.

42. (Canceled)

43. (Previously presented) The device according to claim 18, wherein said first pressure sensor and said second pressure sensor are disposed on a common substrate.

44. (Previously presented) The device according to claim 43, wherein said CPU is disposed on said common substrate.

45. (Previously presented) The device according to claim 25, wherein said differential pressure sensor and said CPU are disposed on a common substrate.

46. (Previously presented) The device according to claim 40, wherein said first pressure sensor and said second pressure sensor are disposed on a common substrate.

Evidence Appendix

No evidence has been submitted by Appellant pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 during the prosecution of this application. Nor has any other evidence been entered by the Examiner and relied upon by Appellant in the appeal.

Related Proceedings Appendix

Pursuant to 37 C.F.R. 41.37(c)(1)(ii), Appellant, the Appellant's legal representative, or the Assignee is not aware of any decisions that have been rendered by a court or the Board in any proceeding that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.